PATENT COOPERATION TREA

Behandeld door	MKe
Adm. opgemaakt	J
Bericht d.d. aan:	
Gearchiv. d.d.	
Alleggen	A

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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PAYS-BAS

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing *(day/month/year)*	18.10.2004
Applicant's or agent's file reference: 2002.738 WO	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP 03/50969	09.12.2003	16.12.2002

Applicant: AKZO NOBEL N.V. et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:	Authorized Officer
European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Pozzi, C Tel. +31 70 340-3260

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 2002.738 WO	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP 03/50969	International filing date *(day/month/year)* 09.12.2003	Priority date *(day/month/year)* 16.12.2002
International Patent Classification (IPC) or both national classification and IPC C12Q1/68		
Applicant AKZO NOBEL N.V. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
10.05.2004	18.10.2004
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer HOCQUET, A Telephone No. +31 70 340-2928

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/50969

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-17 as originally filed

Claims, Numbers

1-11 filed with telefax on 21.07.2004

Drawings, Figures

1-3 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 7,8

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 7,8 are so unclear that no meaningful opinion could be formed *(specify)*:

   see separate sheet

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	3,10,11
	No:	Claims	1,2,4-6,9
Inventive step (IS)	Yes:	Claims	3
	No:	Claims	1,3,4-6,9-11
Industrial applicability (IA)	Yes:	Claims	1-6,9-11
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item III
Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The features added by dependent claims 7 and 8 are features of the delivery device (**flexible** in claim 7 and the composition in claim 8). The delivery device is not part of the claimed vessel. The intended limitations to the claimed vessel are therefore not clear from these claims, contrary to the requirements of Article 6 PCT.

Re Item V
Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents

D1: WO 96/28717 A (CORTECS LTD) 19 September 1996
D2: US-A-3 801 280 (PEOT C ET AL) 2 April 1974
D3: DE 197 25 015 A (BAYER AG) 17 December 1998
D4: DE 198 39 398 A (HOECHST) 16 March 2000

1 The mention that the 'pharmaceutical device' to be retained in the vessel of claim 1 is of annular shape does not bring any clear limitation to the scope of the claim. In the following discussion, it is worth noting that the claims are not at all limited to a specific range of diameters of the delivery device. The description indicates (page 11, lines 24-29) that the diameter of the delivery device can vary widely. A basket or a sinker (such as disclosed in D2-D4) adapted to retain a disc-like tablet up to a certain diameter, is as well adapted to retain a ring-like tablet up to that same diameter. The preferred range mentioned in the application from 3 to 10 cms overlaps the conventional diameters of tablets, but even if the dimensions of the delivery devices considered in the application were outside that range, a skilled person will adapt naturally the dimension of of his dissolution vessel and of his retainer, -whatever shape this retainer has-, to the dimensions of the device the dissolution of which he wants to study, exactly as it is done in the present application (page 5, lines 20-31).

2 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1,2,4,5,9 is not new in the sense of Article 33(2)

PCT: the document **D1** discloses a vessel with one or more projections or a continuous annular projection (see D1, page 4, lines 10-13, page 5, lines 9-16 and reference 2 of figure 1). D1 indicates a solvent volume of 900 ml (page 5, line 34). The internal diameter of the vessel, however not mentioned must therefore be around 10 centimetres (see references to standard dimensions in the application page 5 , lines 20-23), which makes the projection 2 of the vessel represented in D1 adapted to retain a flexible ring-shaped pharmaceutical delivery devices such as considered in the application (page 11, line 21 to page 12, line 11) while allowing the passage to the vessel bottom.

3 As D1 discloses the provision of more than one projection (page 4, lines 10-11), the current wording of claim 6 is also not new, as a plurality of 'bulges' can be seen as forming 'two sets'.

4 Claims 1,10 and 11 are obvious over D2. The retainer 2 of D2 allows the passage of the sampling tube contained in the rod 26. The retainer 2 of the figures is placed in the vicinity of the side wall of the vessel 1 (off-center as noted c 4, l 18) so as to leave the center of the vessel free for the sampling tube and the stirring means (see figures of D2). The problem of positioning a retainer in a vessel without impeding the passage of a sampling tube to the vessel bottom is thus already solved by D2. Even if it is considered that the basket is not 'provided by or at the vessel wall', the difference between the vessel of claims 1, 10 and 11 and the vessel of D2 consists simply in another 'convenient manner' of positioning the retainer 2 in the vessel 1 (D2, column 4, lines 10-12), the requirement being that the retainer is positioned so as to leave the center of the vessel free for the sampling tube and the stirring means. Attaching a basket to the side wall of the vessel (eg by hooks) instead of suspending it to a rod attached to the lid is merely one of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem posed, which was to provide an off-center retainer.

5 Claim 1 is not new over D3 or D4 which discloses free falling (sinking) retainers which are thus provided 'at the bottom' of a vessel and would allow a passageway to the vessel bottom because they are not fixedly attached to the bottom.

7 The combination of the features of dependent claim 3 is neither known from, nor rendered obvious by, the available prior art.

New set of claims (21 July 2004)

CLAIMS

1. A vessel for dissolution testing of a pharmaceutical delivery device, comprising:

an inert vessel wall and an inert vessel bottom such that the vessel is able to hold a fluid medium;

,an inert retainer provided by or at the vessel wall or vessel bottom, for holding an annular pharmaceutical delivery device; and which retainer allows a passageway to the vessel bottom for a sampling tube.

2. A vessel according to claim 1, wherein the vessel wall and vessel bottom together form one transparent glass entity.

3. A vessel according to claim 1 or 2, wherein the retainer comprises an annular plate, which annular plate comprises a passageway for a sampling tube in the middle, and which annular plate is placed inside the vessel at the vessel wall.

4. A vessel according to claim 1 or 2, wherein the retainer is permanently fixed to the vessel wall or vessel bottom.

5. A vessel according to claim 1 or 2, wherein the retainer comprises one or more annular ledges or rims; or one or more bulges; and wherein the annular ledges or rims or the bulges are protruding inwardly from the vessel wall or vessel bottom.

6. A vessel according to claim 1 or 2, wherein the retainer comprises two sets of bulges formed by indentation of the vessel wall or vessel bottom.

7. A vessel according to claim 1 or 2, comprising a retainer provided by or at the vessel wall or vessel bottom, with which retainer a flexible annular pharmaceutical delivery device can be held.

8. A vessel according to claim 8, wherein the flexible annular pharmaceutical delivery device comprises at least one compartment which comprises a thermoplastic polymer core and a thermoplastic polymer skin covering the core, which core comprises a mixture of a progestogenic compound and an estrogenic compound, and which skin is permeable for the progestogenic and estrogenic compounds.

9. A method for preparing a vessel according to anyone of claims 4 to 6 comprising melting or gluing a retainer to the vessel wall or vessel bottom or by applying one or more indentations to the vessel wall or vessel bottom.

10. A method for dissolution testing of a pharmaceutical delivery device, which delivery device contains a pharmaceutically and/or contraceptive effective amount of drug, comprising:

placing a fluid medium and stirring means in a dissolution vessel according to anyone of claims 1-9;

placing a pharmaceutical delivery device in the retainer of the dissolution vessel according to anyone of claims 1-9;

rotating the stirring means to circulate the fluid medium in the dissolution vessel; and

sampling one or more predetermined volumes of the fluid medium at selected time intervals by means of a sampling tube.

11. An apparatus for dissolution testing of a pharmaceutical delivery device, comprising:

one or more dissolution vessels according to anyone of claims 1-9 which dissolution vessels are suitable for holding a fluid medium;

one or more stirring means;

a sampling and/or discharging device with one or more sampling and/or discharging tubes suitable for sampling and/or discharging one or more predetermined volume fractions of the fluid medium from the dissolution vessels; and

optionally, a refilling device suitable for adding fluid medium to the dissolution vessels.